Kentucky Department for Medical Services

Drug Review Options

The following chart lists the agenda items scheduled and the options submitted for review at the March 20, 2008 meeting of the Pharmacy and Therapeutics Advisory Committee.

Item	Options for Consideration
Antimigraine agents - Serotonin (5-HT_1) Receptor Agonists-Triptans almotriptan (Axert®) eletriptan (Relpax™) frovatriptan (Frova™) naratriptan (Amerge®) rizatriptan (Maxalt®) sumatriptan (Imitrex®) zolmitiptan (Zomig®)	1 All triptans and all dosage forms are considered clinically equivalent in efficacy and safety. 2. DMS to select agent(s) as preferred based on economic evaluation. 3) Agents not selected as preferred based on economic evaluation will require PA. 4. Continue to require failure of 2 preferred agents before PA approval of a non-preferred agent. 5. Continue monthly quantity limits per manufacturer's guidelines, with PA required for additional medication. 6. As part of quantity limit override criteria, require the patient to be on concurrent migraine prophylaxis medication (beta blocker, tricyclic antidepressant, calcium channel blocker, etc.) at a therapeutic dose. 7. Require PA for duplicate therapy/concurrent use of triptans by different routes. 8. For any new chemical entity in the triptan class, require a PA until reviewed by the P&T Advisory Committee
Antiemetics, Oral, to Treat Severe Nausea/ Vomiting NK_1 Receptor Anatagonist Class– aprepitant (Emend®) (5-HT_3) Therapeutic Class - dolastron (Anzemet®) granisetron (Kytril®) ondansetron (Zofran®) Cannabinoids Class – dronabinol (Marinol®) nabilone (Cesamet®)	1. All products in the 5-HT_3 class are considered clinically equivalent in efficacy and safety. 2. Select at least two (2) products to be used as preferred based on economic evaluation. 3. Quantity limits (No PA) – Place quantity limits on the 5-HT_3 antagonists and on Emend with the quantity limits based on the average quantity per treatment session (and "x" number of sessions per month), and on available package size of each product. Request for higher doses would require PA. The following are suggested quantity limits based on 4 cancer treatment cycles per month and adjusted for available package sizes. Zofran: 4 mg and 8 mg: 12 tablets per month 24 mg : 4 tablets per month Liquid: 60 ml/month Kytril: 1 mg tablets: 8 tablets per month Liquid 80 mg per month Anzemet: 50 mg and 100 mg tablets: 5 tablets per month Emend: 4 Tri-packs (9 tablets) per month 4. PA required. Approval based on stated chemo agent and/or type of radiation. Quantities restricted to those mentioned in guidelines above and number of requested cancer treatments per month. Non-oncology use will be approved on an individual basis based on prior use of first-line antiemetics.

	5. For any new chemical entity in the Antiemetics 5-HT_3 class, require a PA and quantity limit until reviewed by the P&T Advisory Committee. 6. Cannabinoids should be reserved to second line therapy for chemotherapy induced nausea and vomiting when patients fail to respond adequately to conventional antiemetics, and use monitored closely. Maximum daily dose of 15mg/m^2 4-6 times dailyfor dronabinol; nabilone maximum dose is 6 mg in divided doses. 7. For any new chemical entity in the antiemetics cannabinoid class, require a PA and quantity limit until reviewed by the P&T Advisory Committee.
<u>Anti-infectives:</u> <u>Hepatitis B Agents, oral</u> adefovir dipivoxil (Hepsera®) entecavir (Baraclude™) lamivudine (Epivir HBV®) telbivudine (Tyzeka®)	1. All products in the Hepatitis B oral anti-infectives class are considered clinically equivalent in efficacy and safety in adults. 2. DMS to select agent(s) as preferred based on economic evaluation. 3. Clinical safety and efficacy for adefovir, telbivudine and entecavir has not been established for pediatric use. Appropriate age edits should be entered into the system, requiring clinical PA for these products when prescribed for children. 4. For any new chemical entity in the Antiinfectives: Hepatitis B, oral, class, require a PA until reviewed by the P&T Advisory Committee
<u>Topical Antivirals</u> Denavir Zovirax cream Zovirax oint. Abreva	TCR being produced.
New indications – Immunomodulators- TNF Antagonists adalimumab (Humira®)	1. Current indications for approval of adalimumab in the KY program include rheumatoid arthritis and psoriatic arthritis. 2. Since the original criteria were developed, additional indications were approved by FDA. They include the treatment of Crohn's Disease, ankylosing spondylitis, severe plaque psoriasis and (Juvenile Rheumatoid Arthritis pending). 3. Since the current 2 preferred products now have similar approvals, DMS may elect to combine the criteria for the class. 4. A quantity limit of 4 syringes of 40 mg dose per 30 days may be implemented for month 1, with subsequent months having an allowance of 2 syringes of 40 mg each per rolling 30 days. 5. For any new chemical entity in the TNF Antagonists class, require a PA and quantity limit until reviewed by the P&T Advisory Committee

The following terms will be utilized within the therapeutic monograph to classify medications during Drug Class Reviews. By using these terms, the reviewer will be able to easily identify any clinical differences between the medications within the class being reviewed.

Superior - Following evidence-based review, it is determined that the drug provides a therapeutic advantage, in terms of safety and/or efficacy, over other available products within the same treatment modality.

Equivalent - Following evidence-based review, it is determined that the drug is therapeutically equivalent in both safety and efficacy to other available products within the same treatment modality.

Not Essential - Following evidence-based review, it is determined that the drug has no therapeutic advantage, due to either reduced safety or efficacy, over other available products within the same treatment modality.